

20 May 2016

Our reference: FSCA 2956

Dear

IMPORTANT : URGENT FIELD SAFETY NOTICE
chromID MRSA SMART Ref. 413050 – 413051)

Our records indicate that your laboratory has received the following products. This letter is intended for all chromID MRSA SMART (Ref. 413050-413051) users (product reference and lot numbers included below).

Table 1:

<u>Product Ref Number</u>	<u>Description</u>	<u>Lot Number</u>	<u>Expiry Date</u>
413050	chromID MRSA SMART	1004746750	02-JUN-2016
413050	chromID MRSA SMART	1004727550	25-MAY-2016
413051	chromID MRSA SMART	1004746760	02-JUN-2016

Description of the issue

Based on an aspect defect of the agar detected internally on 3 lots of chromID MRSA SMART (Ref. 413050-413051)- lots: #1004746750, #1004727550 and #1004746760-, bioMérieux initiated a complaint investigation to confirm product performance and determine root cause.

While the investigation is still ongoing, the following have been identified:

- ⇒ The root cause of the issue has been identified as a raw material leading to particles sedimentation defect that did not allow the agar coloration and leads to an opacity defect.
- ⇒ The aspect defect can be sometimes detected by the user prior to the use.
- ⇒ This issue has no impact on the growth of MRSA but **the coloration of small colonies could be delayed** (colorless after 18h of incubation and pink or red color after 24h) on the impacted chromID MRSA SMART plates. Then, if the aspect defect was not detected prior the use, after 18h of incubation colonies could be seen colorless, instead of pink or red.



Impact to Patient/User:

As a result of the opacity issue on chromID MRSA SMART (Ref. 413050-413051) there is a risk of misinterpretation of the result, in case of the issue was not detected prior the use: A clinical sample with a MRSA positive result could be interpreted as a Negative result, small colonies remaining colorless after 18h of incubation.

Required actions:

- Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.
- Discontinue using and discard any remaining inventory chromID MRSA SMART (Ref. 413050-413051)- lots listed Table 1
- Among tests previously performed with these batches, we are asking you to identify any possible false Negative results, analyse the related risks and determine appropriate actions if relevant.
- **Complete and return the Acknowledgement Form in Attachment A for the attention of Customer Service Department to fax number 0044 (0) 1256 816863.**

We can confirm that the Competent Authority has been informed of this action.

bioMérieux is committed to providing our customers with the highest quality product possible. We sincerely apologise for any inconvenience that this may have caused you. If you require additional assistance or have any questions, please contact our Technical Service Department on 0044 (0) 1256 461881.

Yours sincerely

Customer Service Department





Attachment A: Acknowledgement Form – FSCA 2956

In order to comply with Competent Authority Regulations it is important that you complete and return this acknowledgement form

To be returned for the attention of Customer Service Department to fax number 0044 (0) 1256 816863

I acknowledge the receipt of bioMérieux Urgent Field Safety Notice informing this laboratory on the chromID MRSA SMART product issue.

Product : chromID MRSA Smart				
413050	chromID MRSA SMART	1004746750	Number of kits received	
			Number of kits destroyed	
		1004727550	Number of kits received	
			Number of kits destroyed	
413051	chromID MRSA SMART	1004746760	Number of kits received	
			Number of kits destroyed	

I have followed the instructions and implemented the actions as indicated in the Urgent Field Safety Notice.

Have you received reports of illness or injury related to the identified issue?

Yes or No

DATE.....

SIGNATURE :

